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ATTY. DOCKET NO.: CV01382K APPLICANT: Harry R. Davis

SERIAL NO.: 10/057,629

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

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PTO-1449 U.S. DEPARTMENT OF COMMERCE

PATENT AND TRADEMARK OFFICE

### INFORMATION DISCLOSURE STATEMENT BY APPLICANT

10/057,629 CV01382K APPLICANT: Harry R. Davis

ATTY. DOCKET NO .:

FILING DATE: **GROUP**: (Use several sheets if necessary) January 25, 2002 1614 WO 95/28919 NG DU 11/02/95 PCT 31/19 A61K X(abs.) PCT WO 96/00288 01/04/96 C12N 15/12 DV DW WO 96/09827 04/04/96 PCT A61K 31/58 WO 96/16037 05/30/96 PCT DX C07D 205/08 PCT DY WO 96/19987 07/04/96 A61K 31/35 12/19/96 PCT A61K 45/06 DZ WO 96/40255 巾 EΑ WO 97/16455 05/09/97 PCT C07H 3/04 EB WO 97/18304 05/22/97 PCT C12N 15/00 Ш 叫 EC WO 97/25042 07/17/97 PCT **A61K** 31/42 m ED WO 97/28149 08/07/97 PCT C07D 307/79 2 62 EE WO 97/31907 09/04/97 PCT **C07D** 263/56 WO 97/35576 EF 10/02/97 PCT A61K 31/44 WO 97/46238 12/11/97 PCT 31/245 EG A61K WO 98/01100 01/15/98 PCT A61K FH EI WO 98/05331 02/12/98 PCT **A61K** 31/45 EJ WO 98/14179 04/09/98 PCT A61K 9/50 EK WO 98/31360 07/23/98 PCT **A61K** 31/19 WO 98/31361 07/23/98 PCT A61K 31/215 EL X(abs.) WO 98/31366 07/23/98 PCT 31/445 EM A61K WO 98/43081 10/01/98 PCT 33/50 EN **G01N** EO WO 98/46215 10/22/98 PCT 9/20 A61K EP WO 98/47518 10/29/98 PCT A61K 31/715 12/23/98 EQ WO 98/57652 PCT A61K 31/785 ER 04/02/99 WO 99/04815 PCT 45/00 **A61K** X(abs.) FS WO 99/06035 02/11/99 PCT A61K 31/00 EŤ WO 99/06046 02/11/99 PCT 31/455 A61K EU WO 99/09967 03/04/99 PCT A61K 31/00 Ē۷ WO 99/12534 03/18/99 PCT A61K 31/17 X(abs.) EW WO 99/11260 03/11/99 PCT A61K 31/40 EX WO 99/15159 04/01/99 PCT A61K 31/00 EY WO 99/15520 04/01/99 PCT C07D 319/20 X(abs.) EZ WO 99/18072 04/15/99 PCT C07D 205/08 WO 99/20275 FA 04/29/99 PCT A61K 31/47 FB WO 99/20614 PCT 04/29/99 C07D 265/36 WO 99/29300 FC 06/17/99 PCT A61K 9/107 FD WO 99/38498 08/05/99 PCT A61K 31/00 WO 99/38845 PCT FE 08/05/99 213/65 C07D FF WO 99/38850 PCT 08/05/99 237/32 C07D PCT FG WO 99/46232 09/16/99 C07C 62/34 X(abs.) FH WO 99/47123 09/23/99 PCT 9/16 **A61K** FI WO 99/48488 09/30/99 PCT **A61K** 31/00 FJ WO 99/66929 12/29/99 PCT A61K 31/405 WO 99/66930 FK 12/29/99 PCT A61K 31/405 FL WO 00/04011 01/27/00 PCT C07D 319/06 FM WO 00/07617 PCT 02/17/00 **A61K** 38/26 FN WO 00/16749 03/30/00 PCT A61K 9/16 X(abs.)

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### Sheet 2 of U.S. DEPARTMENT OF COMMERCE ATTY. DOCKET NO .: SERIAL NO .: PATENT AND TRADEMARK OFFICE $\overline{\Pi}$ CV01382K 10/057,629 INFORMATION DISCLOSURE STATEMENT APPLICANT: Harry R. Davis BY APPLICANT FILING DATE: GROUP: (Use several sheets if necessary) January 25, 2002 1614 03/18/92 EUROPE EP 0475148 A1 **A61K** 31/215 EP 0475755 B1 03/18/92 **EUROPE** C07D 403/06 BW BX EP 0481671 A1 04/22/92 **EUROPE** C07D 205/08 BY EP 0482498 A3 04/29/92 EUROPE **A61K** 31/66 BZ EP 0524595 A1 01/27/93 **EUROPE C07D** 205/08 CA | EP 0720599 B1 07/10/96 EUROPE C07D 205/08 CB EP 0793958 A2 09/10/97 **EUROPE** A61K 9/16 X(abs) CC | EP 0814080 A1 12/29/97 EUROPE **C07D** 267/14 EP 0904781 A2 **A61K** CD 03/31/99 EUROPE 31/215 CE EP 1048295 A2 11/02/00 EUROPE A61K 31/216 10/31/55 **FRANCE** Х CF FR 1103113 FR 2779347 12/10/97 **FRANCE** A61 031/215 X(abs.) CG **A61K** CH GB 861367 02/22/61 GB CI GB 902658 08/09/62 GB C07D C07C 59/26 CJ GB 1415295 11/26/75 GB CK GB 2329334 A 03/24/99 GB A61K 45/00 CL JP 028057 10/01/81 **JAPAN** X(abs. СМ JP 121479 12/10/86 **JAPAN** X(abs.) JP 136485 **JAPAN** X(abs.) ÇN 05/26/81 JP 180212 03/24/86 **JAPAN** X(abs. CO CP JP 219681 04/14/87 **JAPAN** X(abs. 031/22 CQ JP 5194209 A 08/03/93 **JAPAN** A61K X(abs.) CR JP 5239020 A 1993 **JAPAN C07D** 205/08 X(abs.) CS JP 4054182 A 1992 **JAPAN** C<sub>12</sub>P 017/16 X(abs.) CT JP 63017859 A 1988 **JAPAN** C07D 205/08 X(abs.) 1992 JAPAN C07D 205/08 CU JP 4266869 A X(abs.) JAPAN CV JP 4356195 A 1993 X(abs.) CW JP 4356495 12/10/92 **JAPAN** X(abs. CX. JP 5058993 A 1993 **JAPAN** X(abs.) CY JP 61280295 A 1987 **JAPAN** X(abs.) CZ 06/05/95 **JAPAN** C07D 205/08 JP 95051558 B2 X(abs.) 10/25/91 205/08 DA JP 91068020 **JAPAN** CO7D X(abs.) DB JP 94047573 06/22/94 **JAPAN** C07D 205/08 X(abs.) DC WO 82/01649 05/27/82 PCT 9/52 X(abs.) A61K DD WO 87/04429 07/30/87 PCT C07D 205/08 DE WO 88/04656 06/30/88 PCT C07D 405/04 DF WO 88/05296 07/28/88 PCT **A61K** 31/365 DG WO 91/03249 03/21/91 PCT A61K 31/785 X(abs.) DH WO 92/13837 PCT C07D 205/085 08/20/92 DI WO 93/02048 02/04/93 PCT C07D 205/08 ŧ DJ WO 93/07167 PCT C07J 71/00 04/15/93 Ł DK WO 93/11150 06/10/93 PCT C07J 71/00 DL WO 94/00480 01/06/94 PCT C07J 71/00 DM WO 94/14433 07/07/94 PCT A61K 31/395 DN WO 94/17038 08/04/94 PCT **C07D** 205/12 DO WO 94/20535 09/15/94 PCT C07K 13/00 DP WO 95/04533 02/16/95 PCT 31/445 **A61K** DQ WO 95/06470 03/09/95 PCT **A61K** 31/435 DR WO 95/08532 PCT 03/30/95 C07D 205/08

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Sheet of

SERIAL NO.: 10/057,629

	PATENT AND TRADEMARK OFFICE
INFORMATION	DISCLOSURE STATEMENT

U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE BY APPLICANT

ATTY. DOCKET NO.: CV01382K APPLICANT: Harry R. Davis

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NG	DU	WO 95/28919	11/02/95	PCT	<del>                                    </del>	A61K	31/19	X(abs.)	Ι—	ヿ゙
	DV	WO 96/00288	01/04/96	PCT		C12N	15/12	<del>  ``                                  </del>	-	٦
	DW	WO 96/09827	04/04/96	PCT		A61K	31/58		-	$\dashv$
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	DY	WO 96/19987	07/04/96	PCT	- MI	A61K	31/35	모		‡
	DZ	WO 96/40255	12/19/96	PCT		A61K	45/06			市
	EA	WO 97/16455	05/09/97	PCT		C07H	3/04	CE I	2	ť
	EB	WO 97/18304	05/22/97	PCT		C12N	15/00	显		Ť
	EC	WO 97/25042	07/17/97	PCT		A61K	31/42		22	
	ED	WO 97/28149	08/07/97	PCT		C07D	307/79	68	2003	*
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	EH	WO 98/01100	01/15/98	PCT		A61K			·	┨
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	EJ	WO 98/14179	04/09/98	PCT		A61K	9/50			$\dashv$
	EK	WO 98/31360	07/23/98	PCT		A61K	31/19	<del> </del>		$\dashv$
	EL	WO 98/31361	07/23/98	PCT		A61K	31/215	X(abs.)	-	$\dashv$
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	ER	WO 99/04815	04/02/99	PCT		A61K	45/00	X(abs.)		$\dashv$
	ES	WO 99/06035	02/11/99	PCT		A61K	31/00	A(aus.)		$\dashv$
	ET	WO 99/06046	02/11/99	PCT		A61K	31/455		-	$\dashv$
	EU	WO 99/09967	03/04/99	PCT		A61K	31/00			$\dashv$
	EV	WO 99/12534	03/18/99	PCT		A61K	31/17	X(abs.)		$\dashv$
	EW	WO 99/11260	03/11/99	PCT		A61K	31/40	A(aus.)		$\dashv$
	EX	WO 99/15159	04/01/99	PCT		A61K	31/00			$\dashv$
	EY	WO 99/15520	04/01/99	PCT		C07D	319/20	X(abs.)		$\dashv$
	EZ	WO 99/18072	04/01/99	PCT		C07D	205/08	^(aus.)		$\dashv$
	FA	WO 99/20275	04/19/99	PCT		A61K	31/47			$\dashv$
	FB	WO 99/20614	04/29/99	PCT		C07D	265/36			$\dashv$
	FC	WO 99/29300	06/17/99	PCT		A61K	9/107			$\dashv$
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	FJ	WO 99/66929	12/29/99	PCT		A61K	31/405			4
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	GA	WO 00/31548	06/02/00	PCT		G01N	33/68		<u> </u>
	GB	WO 00/32189	06/08/00	PCT		A61K	31/415		
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	GS	WO 00/53173	09/14/00	PCT	<del></del>	A61K	31/22	V(-b - 1	$\vdash$
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	GU	WO 00/56403	09/28/00	PCT		A61P	9/10		
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	GW	WO 00/57918	10/05/00	PCT		A61K	47/44		igsqcup
	GX	WO 00/60107	10/12/00	PCT		C12P	17/10		
	GY	WO 00/63153	10/26/00	PCT		C07C	69/734		<b> </b>
	GZ	WO 00/63161	10/26/00	PCT		C07C	237/30	ļ	
	HA	WO 00/63190	10/26/00	PCT		C07D	265/38		igsqcut
	нв	WO 00/63196	10/26/00	PCT		C07D	277/04		
	нс	WO 00/63209	10/26/00	PCT	RECEIV	C07D	471/04		
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	HF	WO 00/69445	11/23/00				A61K	9/14		
	HG	WO 00/72825	12/7/00	PCT			A61K	9/14		
<b></b>	HH	WO 00/72829	12/07/00	PCT alybran	<del>- 100</del>		A61K		V(aba)	
	HI	WO 00/75103	12/14/00	PCT almbrow	00		A61K	235/60 9/48	X(abs.)	
	HJ	WO 00/76482	12/21/00	PCT			A61K	31/00		
	HK	WO 00/76488	12/21/00	· .			A61K	31/421		
$\vdash$	HL	WO 00/78312	12/28/00	PCT PCT			A61K	31/422		
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<b></b>	HN	WO 01/00579	01/04/01	PCT			C07D	277/24		
	HO	WO 01/00603	01/04/01	PCT				31/495		
	HP	WO 01/08686	02/08/01				A61K	L		
<b> </b>	HQ	WO 01/12176	02/22/01	PCT	141		A61K	31/16	<u> </u>	
	HR	WO 01/12187	02/22/01	PCT			A61K	31/404	<u></u>	
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	HW	WO 01/15744	03/08/01	PCT	···		A61K	49/00		
	НХ	WO 01/16120	03/08/01	PCT			C07D	263/32		
	HY	WO 01/17994	03/15/01	PCT			C07D	413/12		
	HZ	WO 01/18210	03/15/01	PCT		ý.	C12N	15/12		
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	IB	WO 01/21259	03/29/01	PCT			A61P			
	IC	WO 01/21578	03/29/01	PCT white	wt_		C07C	235/60	X(abs.)	
	ID	WO 01/21647	03/29/01	PCT			C07K	14/00		
	IE	WO 01/22962	04/05/01	PCT			A61K	31/435		
<u> </u>	IF	WO 01/25225	04/12/01	PCT			C07D	317/18		
	IG	WO 01/25226	04/12/01	PCT			C07D	327/04		
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Sheet <u>3</u> of <u>9</u>

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		JB	WO 02/26729	04/04/02	PCT		C07D	311/66		<u> </u>
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			3-substituents into							
		JL	Nobuki, O. et al., "							
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Sheet of U.S. DEPARTMENT OF COMMERCE **FORM PTO-1449** ATTY. DOCKET NO .: SERIAL NO.: PATENT AND TRADEMARK OFFICE CV01382K 10/057,629 APPLICANT: INFORMATION DISCLOSURE STATEMENT Harry R. Davis **BY APPLICANT** FILING DATE: GROUP: (Use several sheets if necessary) January 25, 2002 1614 OB P.F. Belamarich et al., "Response to Diet and Cholestyramine in a Patient with M Sitosterolemia", Pediatrics, 977-981, (December 1990) G. Salen et al., "Lethal Atherosclerosis Associated With Abnormal Plasma and Tissue OC Sterol Composition in Sitosterolemia With Xanthomatosis", Journal of Lipid Research, 1126-1133, (September 1985) OD G.R. Thompson et al., "Novel Lipid-Regulating Drugs, Exp. Opin. Invest. Drugs, 9(11):2619-2628, 2000 OE International Search Report dated December 18, 2002 corresponding to PCT ΜY Application No. PCT/US02/01195 DATE CONSIDERED 16/41/67

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APR 1 5 2003 TECH CENTER 1600/2900 70-1449 SERIAL NO.: U.S. DEPARTMENT OF COMMERCE ATTY, DOCKET NO .: PATENT AND TRADEMARK OFFICE CV01382K 10/057,629 APPLICANT: INFORMATION DISCLOSURE STATEMENT Harry R. Davis BY APPLICANT GROUP: FILING DATE: (Use several sheets if necessary) January 25, 2002 1614 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) AA | Exhibit A: SCH 58235 Micronized (ezetimibe), Drug Formulation Development Summary AB | Exhibit B: SCH 58235 (ezetimibe), Drug Formulation Development Summary AC Exhibit C: SCH 58235 (ezetimibe), Drug Formulation Development Summary AD Exhibit D: SCH 58235 (ezetimibe), Drug Formulation Development Summary AE Exhibit E: SCH 58235 (ezetimibe), Drug Formulation Development Summary AF | Exhibit F: SCH 58235 (ezetimibe), Drug Formulation Development Summary AG | Exhibit G: SCH 58235 (ezetimibe), Drug Formulation Development Summary AH | Exhibit H: SCH 58235 (ezetimibe), Drug Formulation Development Summary Exhibit 1: Master Sheet for the SCH 58235 and Lovastatin Research Study, Schering-Plough Research Institute (Protocol No. C906-411), page 1576-1585 Exhibit 2: Medical Research Study #1055/97, SCH 58235: Bioavailability of Single Oral Doses AJ of Two Prototype Tablet Formulations and the Reference Capsule Formulation of SCH 58235 in Normal Male Volunteers: A Four Way Crossover Study #C97-221-01, Informed Consent, Peninsular Testing Corporation, page 106-112 AK Exhibit 3: Consent Form to Participate in a Research Study, "A Phase II Double Blind Dose Response Investigation of Efficacy and Safety of Four Doses of SCH 58235 Compared to Placebo in Subjects with Primary Hypercholesterolemia," Schering-Plough Research Institute

Between 58235 and Gemfibrozil in Healthy Volunteers," Schering-Plough Research Institute, page **EXAMINER** DATE CONSIDERED 16/03

(Protocol No. C98-010), page 1558-1566

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line throught citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Exhibit 4: Medical Research Study #1096/99, SCH 58235: Pharmacokinetic Pharmacodynamic

Drug Interaction Study with Digoxin in Healthy Volunteers #C98-114, Informed Consent,

Exhibit 5: Informed Consent, "SCH 58235: Assessment of Multiple-Dose Drug Interaction

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# TECH CENTER 1600/2900

HORMATO-1449  U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			ATTY. DOCKET NO.: SERIAL NO.: CV01382K 10/057,629						
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